enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a non-hygroscopic dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates.

21. (Amended) A method for systemic administration of a pharmaceutically active polypeptide, comprising

providing a composition comprising a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of the polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device; and

causing said patient to inhale through the mouth said composition from a dry powder inhaler device; provided that at least 50% of the total mass of the active compounds, at the point the active compounds enter the respiratory tract of the patient, consists of particles having a diameter less than or equal to about 10 microns.

Add new claims 61-100.

--61. A pharmaceutical composition, comprising a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates; and

a pharmaceutically acceptable carrier comprising particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.--

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--62. The composition of claim 61, wherein said polypeptide is a polypeptide hormone.--

--63. The composition of claim 62, wherein said hormone is vasopressin, a biologically active analogue of vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth

hormone (HGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), a biologically active analogue of somatostatin, a biologically active analogue of gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.--

--64. The composition of claim 61, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.--

--65. The composition of claim 61, wherein said polypeptide has a molecular weight of less than 30 kD.--

--66. The composition of claim 61, wherein said polypeptide has a molecular weight of less than 25 kD.--

--67. The composition of claim 61, wherein said polypeptide has a molecular weight of less than 20 kD.--

--68. The composition of claim 61, wherein said polypeptide has a molecular weight of less than 15 kD.--

--69. The composition of claim 61, wherein said polypeptide has a molecular weight of less than 10 kD.--

--70. The composition of claim 61, wherein said enhancer compound is a surfactant.--

--71. The composition of claim 70, wherein said surfactant is a bile salt, a bile salt derivative, an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.--

--72. The composition of claim 70, wherein said surfactant is a salt of a fatty acid.--

--73. The composition of claim 72, wherein said fatty acid has 10-14 carbon atoms.--

--74. The composition of claim 73, wherein said fatty acid is capric acid.--

--75. The composition of claim 70, wherein said surfactant is sodium caprate.--

--76. The composition of claim 61, wherein aid enhancer compound is a bile salt.--

--77. The composition of claim 76, wherein said bile salt is sodium taurocholate.--

--78. A dry powder inhaler device containing a pharmaceutical composition comprising a mixture of active compounds (A) a pharmaceutically active polypeptide, and (B) an enhancer compound which (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of active compounds consists of primary particles having a diameter less than or equal to about 10 microns, said primary particles optionally being formed into agglomerates; the dry powder inhaler device being adapted for inhalation through the mouth.--

E4 cont

--79. The dry powder inhaler device of claim 78, wherein the pharmaceutical composition comprises a pharmaceutically acceptable carrier, which comprises either

(a) particles having a diameter of less than about 10 microns, such that at least 50% of said composition consists of optionally agglomerated primary particles having a diameter of less than about 10 microns; or

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(b) particles having a diameter of at least 20 microns, such that an ordered mixture is formed between the active compounds and the carrier.--

--80. The dry powder inhaler device of claim 78, wherein said polypeptide is a polypeptide hormone.--

--81. The dry powder inhaler device of claim 80, wherein said hormone is vasopressin, a biologically active analogue of vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), a biologically active analogue of somatostatin, a biologically active analogue of gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.--

--82. The dry powder inhaler device of claim 78, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.--

--83. The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 30 kD.--

--84. The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 25 kD.--

--85. The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 20 kD.--

--86. The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 15 kD.--

--87. The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 10 kD.--

--88. The dry powder inhaler device of claim 78, wherein said enhancer compound is a surfactant.--

--89. The dry powder inhaler device of claim 88, wherein said surfactant is a bile salt, a bile salt derivative, an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.--

--90. The dry powder inhaler device of claim 88, wherein said surfactant is a salt of a fatty acid.--

--91. The dry powder inhaler device of claim 90, wherein said fatty acid has 10-14 carbon atoms.--

--92. The dry powder inhaler device of claim 91, wherein said fatty acid is capric acid.--

--93. The dry powder inhaler device of claim 88, wherein said surfactant is sodium caprate.--

--94. The dry powder inhaler device of claim 78, wherein said enhancer compound is a bile salt.--

--95. The dry powder inhaler device of claim 94, wherein said bile salt is sodium taurocholate.--

--96. The dry powder inhaler device of claim 78, wherein said composition is in the form of said agglomerates, said device being configured to induce the majority of said agglomerates to break down into particles having a diameter less than or equal to about 10 microns, upon inhalation of said agglomerates from said device.--

--97. The dry powder inhaler device of claim 78, said inhaler device being a multi dose, breath actuated, dry powder inhaler for multiple use.--